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MAN

THOMAS G. BRUTON  
CLERK, U.S. DISTRICT COURT

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS

MARY MADISON,

Plaintiff,

v.

Case No. 23CV16476

Honorable Judge Manish S. Shah

CREATIVE WERKS, LLC,

and Steve Schroeder, individually,

Defendants.

PLAINTIFF'S RESPONSE TO DEFENDANTS' RULE 56.1 STATEMENT OF UNDISPUTED  
MATERIAL FACTS AND STATEMENT OF ADDITIONAL MATERIAL FACTS

I. Response to Defendants' Statement of Undisputed Material Facts

**1.** Denied. Defendants denied this in their Answer. (Answer ¶11(b), Dkt. #53.)

**2.** Admitted.

**3.** Denied in part. The FDA inspection report outlines the responsibilities of individuals engaged in regulatory operations. Defendants have admitted that Mr. Zicher was involved in compliance-related functions (Answer ¶7, Dkt. #53) and that Plaintiff was hired for her regulatory and quality expertise (Answer ¶8, Dkt. #53). Although Zicher held a PCQI

certification, such certification is not mandatory under the Food Safety Modernization Act (FSMA); compliance is determined by the adequacy of the Food Safety Plan, not by individual credentials. See 21 C.F.R. § 117.180(c)(1).

Under *Coleman v. Donahoe*, 667 F.3d 835, 846–47 (7th Cir. 2012), comparators need not have identical job duties but must be similarly situated in all material respects. Both Plaintiff and Zicher participated in FDA inspections and shared responsibility for quality and compliance. Defendants further admitted that Mr. Schroeder discussed the FDA audit with both individuals and that questions initially posed to Zicher were redirected to Plaintiff for response (Answer ¶¶, Dkt. #53). These admissions support the conclusion that Plaintiff and Zicher were similarly situated for purposes of comparator analysis.

**4.** Admitted.

**5.** Admitted.

**6.** Admitted in part. The FDA informed Defendants that they were coming. The reason for the visit stemmed from a consumer complaint (170623), Plaintiff's compl. Dkt # 1 & Dkt. # 81-1 Exhibit 2 pg. 59#1) Zicher confirms that the initial visit was focused on the consumer complaint (Def. Exhibit 3, pg 75 Dkt. #81), encompassing the issue cited in Zicher's email. Defendants' facility had not been registered and hence necessitating a routine inspection. The FDA report (Def. Exhibit 2-Dkt. #81) indicates that this was the Defendants' first inspection (pg. 58) since the enactment of FSMA in 2011. Defendants admit that they have been in business since 1999 (Dkt #81-¶11 pg 4)

**7.** Denied in part. The FDA consumer complaint indicates that Pepsi contacted Defendants about the adulterated Cheeto product as a direct result of a consumer complaint. (Dkt. #1-consumer

complaint; See also Def. Ex 2 pg. 58) It is admitted by Defendants that there was a prior similar customer complaint, evidencing repeated introduction of adulterated product into the stream of commerce in violation of the FFDCA.

**8.** Denied in part, the FDA report states that the consumer became ill after eating the Cheeto product and asserted that black mold was present. (Dkt. #81-Exhibit 2 pg 59)

**9.** Admitted in part that the product was no longer packaged at Creative Werks during Plaintiff's tenure. Plaintiff cannot either confirm or deny the remaining assertions.

**10.** Denied in part. While Defendants reference a third-party audit, it was not conducted under FDA authority and does not establish FSMA compliance. Third-party audits are voluntary and Plaintiff disputes that the audit validated systemic compliance with FSMA. (Madison Declaration-; Defendants Ex. 6 Nestlé Audit-Dkt 81; FDA Report- Exhibit 2-Dkt 81.) Further, Plaintiff contests its sufficiency under applicable federal standards. Additionally, the FDA noted in Def. Exhibit 2 Dkt. 81 that this was Defendants' first inspection pg. 58. Further, the FDA inspector indicated that due to the facility not being registered as required, the facility had not been inspected. Every customer of the Defendants that manufactures, handles, or packs food products or food-related products is regulated by the FDA.

**11.** Denied in part. Although Defendants reference audit records, Plaintiff contests their relevance under FSMA. These records do not resolve the hazard analysis and preventive controls deficiencies or the various other subparts of 21 CFR 117 identified in Plaintiff's Risk Analysis. (See Ex. 2; FDA Report- DKT 81; and in the SQF report (Def. Exhibit 5-Dkt. #81) and Nestle audit (Def. Exhibit 6 Dkt. #81 pg 3) that further references 31 non-conformances (13 Major and 18 Minor). Although the audit records may exist, they do not address the systemic concerns

raised by Plaintiff, nor do they provide FSMA validation or include corrective actions required by law.

**12.** Denied in part. Plaintiff acknowledges the audit date but contests the scope and effectiveness of the review. Defendants failed to address FDA-reported violations and internal inconsistencies with Zicher's Food Safety Plan. (Dkt. 81 & Plaintiff's Undisputed Facts Stmt. ¶14, ¶49–50.) Plaintiff acknowledges the audit date but disputes the completeness and conclusions drawn by Defendants, given the concerns noted in the FDA report (Def. Exhibit 2 pg. 58), subsequent compliance failures and unresolved safety risks.

**13.** Denied in part. The existence of audits is not disputed, but Plaintiff denies they reflect adequate FSMA compliance. The audit omitted material risk factors that were documented in Plaintiff's Risk Analysis and third-party observations. (See Def. Ex. 2 & 6-Dkt #81.) Further, the FDA report states that a comprehensive audit was not conducted (Def. Exhibit 2 pg. 67) Plaintiff does not contest the occurrence of audits but denies that they demonstrate compliance with FSMA requirements or correct the violations she documented.

**14.** Denied in part. Plaintiff challenges the reliability of audit conclusions due to known recurring violations. These audits were not comprehensive and failed to reflect systemic non-compliance patterns noted by Plaintiff and corroborated by the FDA. (FDA Report; Def. Ex. 2; Pl.'s Undisputed Stmt. ¶49–52.) Plaintiff disputes Defendants' interpretation of "NAI" as it was clearly noted in the FDA report that five (5) concerns/observations were made and that Zicher promised to correct these non-conformances (Def. Exhibit 2 pg. 58). Additionally, as stated, the FDA admits that it did not conduct a full-on audit. (DKT #81-Exhibit 2 pg. 67). The FDA audit was not a reliable indicator of FSMA compliance due to repeated consumer complaints (DKT #1-consumer complaint exhibits), infractions—Nestle audit (Def. Exhibit 6-Defendants' Exhibit

is not representative of the outstanding non-conformances during the relevant time of Plaintiff's employment. The document as represented has all of the outstanding issues closed and that was not the case during the relevant time. See Plaintiff's declaration, Exhibit 10 and lack of proper documentation supporting compliance controls (Def. Exhibit 6-Dkt #81)

**15.** Denied in part. 483 notices are issued or not issued at the discretion of the FDA inspector. There were five (5) observations made and noted by the FDA inspector with the understanding that these issues would be remediated. (Def. Exhibit 2- pg 58 Dkt. #81) Third-party audits, including the Nestlé audit, were voluntary and not substitutes for regulatory compliance. Plaintiff's Risk Analysis identified uncorrected FSMA violations which Defendants failed to address, despite internal acknowledgment. (Answer ¶8, Dkt. #53; Ex. 2.) The third-party audits cited by Defendants were voluntary and not conducted under FDA protocols. Plaintiff's Risk Analysis identified key regulatory violations not reflected in those audits.

**16.** Admitted in part. Defendants' omitted Plaintiff's attachment relative to the email that was sent. Further, these emails went to Schroeder, LeMay and Sammath, among other salaried employees of Creative Werks as evidenced by the emails. Pointedly, Zicher sent two (2) emails, one on September 28 and another on September 29, 2022, discussing the Cheeto investigation in both emails and renumbering the five (5) observations noted by the FDA inspector on September 29, 2022 (Def. Exhibits 2 & 3 Dkt. #81).

**17.** Denied in part. The cited audit fails to address the same operational and regulatory deficiencies identified by Plaintiff. Independent review and expert testimony corroborate Plaintiff's findings (Madison Declaration-Exhibit 27 (Dr. Hutt report). Plaintiff disputes the interpretation of the audit's conclusions, as Defendants failed to acknowledge deficiencies documented in Plaintiff's Risk Analysis, FDA inspection reports, third-party SQF audits, and

customer audits. Moreover, Plaintiff lacks knowledge of any events occurring after her suspension and exclusion from Defendants' facility in 2023 and therefore cannot admit to any assertions based on post-suspension conduct.

**18.** Denied in part. Third-party audits may be required by customers, but are not a requisites of the FDA under FSMA. Plaintiff denies that the audit scope included preventive controls, allergen management, change management and other hazard identification metrics as required under FSMA (Def. Exhibit 6 Dkt. #81). Defendants fail to show that such items were properly audited. Plaintiff challenges the characterization of the audit scope and its sufficiency to validate systemic food safety risks identified under her role.

**19.** Denied in part. Plaintiff identified documented gaps in record keeping, sanitation, traceability etc...that were not captured in Defendants' audit, considering that the standards are not the same. These were confirmed in third-party and Nestlé audit reviews. (Ex. 6-Dket # 81) While audit outcomes are acknowledged, Plaintiff denies they reflect lawful compliance due to substantive and repeated control gaps she documented. Further, Plaintiff denies reviewing the March 29, 2023, SQF audit. Further, admitting a rating on a voluntary audit does not equate to regulatory compliance.

**20.** Denied in part. Plaintiff's Risk Analysis relied on federal standards under FSMA and was corroborated by internal email communications and audit failings. The audits cited by Defendants do not rebut or nullify those findings. (Dkt #53 and 81) Plaintiff disputes that the audits negate or supersede her Risk Analysis, which was based on FSMA statutory requirements and professional judgment as a regulatory professional. Further, Defendants referenced Exhibit 6 (Dkt #81) identifies 31 non-conformances, 13 which are major findings and 18 minor findings.

Further, by Defendants' own admission these customers are regulated by the FDA and in turn require that its agents comply with these same guidelines.

**21.** Denied in part. The record shows repeated compliance failures and systemic gaps that were not resolved through third-party audit activity. Defendants' own expert and Zicher disagreed on the adequacy of the compliance program. (Declaration of Zicher to the Department of Labour and Declaration of Knunton 2023) Creative Werks underwent third-party audits, which are voluntary and do not equate to FSMA compliance. The audits identified systemic and repeated compliance failures. (Def. Ex. 2 Dkt #81)

**22.** Admitted in part. To the extent that was the directive given by Zicher; however, this was not the correct standard as Food Safety Plans are requisite of FSMA. Just as the FDA inspector stated that Zicher's work product was hard to read and understand and had errors ( Def. Exhibit 2 Dkt #81 pg 71), Plaintiff had that same experience as the FDA inspector with the food safety plan being hard to read and understand and filled with errors that Zicher had provided to her.

**23.** Admitted in part. Plaintiff objects to Defendants referring to the risk analysis as a legal analysis. That is a mischaracterization of the document presented to Schroeder on October 21, 2022. Further, the referenced exhibits to the Risk Analysis were omitted.

**24.** Denied in part. While Defendants claim an open-door policy, LeMay did not follow through with meeting Plaintiff. (Answer ¶19, 55-57 & fn. 88 Dkt. #53.)

**25.** Denied in part. To the extent that the Risk Analysis was shared with the individuals, as stated by Defendants, the only individual who arguably has the requisite knowledge to derive the conclusion proffered is Zicher and to which any statements made by Zicher are self-serving.

Plaintiff is not aware of whom the Risk Analysis was subsequently shared with, as Plaintiff was excluded from any internal investigations. (Dkt #53 ¶75)

**26.** Denied in part. FDA and Nestlé audit reports confirmed issues similar to those raised by Plaintiff, including that documents prepared by Zicher were hard to understand and inaccurate. (Def. Ex. 2, pg. 71 and Ex. 6) Plaintiff addressed these various issues with Zicher over the course of time and attempted to address issues through HR (Dkt #81 ¶24). Defendants' open-door policy is acknowledged in their Answer. (Answer ¶19, 55-57 & fn. 88 Dkt. #53.) The FDA report confirmed that the food safety documents created under Zicher's leadership were confusing and error-prone. (Ex. 2; Ex. 2, pg. 71) The Nestlé audit report demonstrated repeated deficiencies and non-conformances (Def. Exhibit 6 Dkt. #81) and further admitted by Defendants ¶20 Dkt #81.

**27.** Denied in part. Plaintiff was never informed that she was being suspended for the unprofessional report. This is in contradiction to Def. Exhibit 10-Dkt.#81 that states the suspension was for the report tendered to Schoreder and the conversation. Plaintiff was excluded from Defendants' internal investigation despite being central to the compliance concerns. (Dkt. #53 ¶75).

**28.** Denied in part. Defendants retained outside counsel to question Plaintiff after her suspension, not as part of an internal review. (Dkt. #53 ¶75-Pl's. Undisputed facts 62 & 68). Plaintiff was suspended on October 26, 2022, and excluded from the internal investigation(Dkt. #53 ¶75; see also Dkt 81). Defendants asserted to Plaintiff that the outside counsel was an independent fact finder (Dkt. #53 ¶82) She was later interviewed by outside counsel on December 20, 2022, where her counsel was present. The outside counsel later claimed privilege and refused to provide the investigation findings (Dkt. #53 ¶93).

**29.** Admitted in part. However, this was not the first time Plaintiff raised issues of disparate treatment—This issue was raised on November 1 and 8, 2022, and again on December 20, 2022, in addition to January 23, 2023. Madison Declaration

**30.** Admitted in part. Prior to January 23, 2023 Plaintiff had not filed any legal action against Defendants. However, Plaintiff continued raising regulatory issues after her suspension, beginning in November of 2022, including on December 20, 2022, during the meeting with outside counsel, and again in January 2023. *Ibid*

**31.** Deny the mischaracterization of the Risk Analysis as a Legal Analysis. Admitted in part that Plaintiff did state that inherent compliance failures can create irreparable harms to all stakeholders. Defendants contradict themselves when they state that they have had dozens of regulatory audits, whereas the FDA report states that the September 2022 audit was the Defendants' first audit. (Def. Exhibit 2 page 58). SQF Def. Exhibit 5 and other third-party audits do not comport to FSMA compliance. Additionally, Defendants' statements about Plaintiff's report are sheer conjecture and can not be substantiated by fact, science or law.

**32.** Denied. Plaintiff possesses a Master's in Regulatory Science from Johns Hopkins, a Chemistry degree, and holds PCQI credentials, and is a certified ISO 9001 and Food Safety Lead Auditor. Plaintiff's education and professional certifications demonstrate expertise consistent with the regulatory assessments she provided. (Dkt.#53 ¶8). There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**33.** Denied. Defendants and Defendants' customers are regulated by the FDA and are subject to the statutory and regulatory scheme promulgated by Congress. Further Plaintiff did not have to read the agreements between Defendants and its customers, because regulatory and statutory

constructs supersede all other agreements and are the controlling requisities. Plaintiff's role and responsibilities at Creative Werks included, but were not limited to, evaluating FSMA compliance and overseeing Food Safety Plans (Answer ¶8, Dkt. #53).

**34.** Denied. Plaintiff's Risk Analysis was grounded in FSMA-mandated practices for hazard identification and preventive controls. Failing to comply with FSMA would inherently result in a breach of contract and fiduciary duty to the customer under FSMA. There is a mischaracterization by Defendants of the Risk Analysis as a Legal Analysis.

**35.** Denied in part. There is a mischaracterization of the Risk Analysis as a Legal Analysis. Admitted in part that Defendants have not been compliant with the Preventive Controls regulations. Defendants Exhibit 5 Dkt #81 SQF audit states that Defendants do not have any Preventive Process Controls (PPC's) and identified it as a non-conformity. A food safety plan cannot exist without Preventive Process Controls (PPC's). Nestle's audit also identifies non-conformities relative to Hazard Analysis and Critical Control Points (HACCP) (Defendants Exhibit 6 (Dkt #81), Plaintiff's declaration Exhibit 6 and 10; Dr. Catherine Hutt Exhibit 27). Plaintiff's Risk Analysis applied the statutory and scientific framework expected of FSMA PCQI personnel.

**36.** Denied. There is no evidence that Plaintiff's methods were deficient. Instead, Defendants failed to address her documented concerns. (Dkt.#40, 53 & 81) Further, there was a similar situation with Med-Fast in October of 2022, who raised concerns about several of Defendants' operational practices (Complaint-Dkt. #1) Further, lost business is not limited to current customer retention, but also extends to loss business opportunities rooted in non-compliance or the lack of evidence in complying with prevailing mandates.

**37.** Admitted in part, but denied in that there is a mischaracterization of the Risk Analysis as a Legal Analysis. Plaintiff holds relevant degrees and certifications in Business Analytics from Harvard University and based her Risk Analysis on FSMA statutory frameworks. Plaintiff contends under the FDA's traceability rule that Defendants had a legal burden to discharge that it admits that it believes does not exist.(Dkt #81 ¶74)

**38.** Admitted in part. Plaintiff identified multiple FSMA violations, including insufficient hazard controls and poor documentation practices. (Def. Ex 2 pg 58 and Ex. 6, Dkt #1) This alone would not allow Pepsi or any other company to discharge themselves of their legal burdens under FSMA. Plaintiff's concerns were based on FSMA standards and gaps in food safety procedures.

**39.** Admit in part and Plaintiff asserts that there is a mischaracterization of the Risk Analysis as a Legal Analysis. Defendants never provided evidence that Plaintiff's findings were scientifically or statutorily invalid or that they conducted an independent scientific or statutory review. (Dkt.#40, 53, & 81). In addition to Plaintiff raising these regulatory issues, the Nestle audit also supports regulatory non-compliance, as well as the FDA report that outlines the regulatory framework. Defendants have no metrics or systems in place to support compliance with the framework identified in the FDA report.

**40.** Denied. Plaintiff's compliance findings were based on document review and comparison to FSMA requirements-21 CFR 117 and the relevant subparts, not speculation. There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**41.** Denied. Plaintiff's use of risk analysis is aligned with FSMA methodology, and her assessments were specific, documented, and tied to statutory obligations. (Def. Ex. 3-Dkt #81)

Defendants abandoned their expert witness in favour of Zicher and Schroeder to support regulatory compliance and interpretation (Dkt. #81)

**42.** Denied. There is no record of Plaintiff's recommendations being formally reviewed and rebutted by Defendants or any qualified food safety expert. (Dkt. 40, 53, &81) Further, the FDA report states that the consumer became ill after eating the Cheeto product. Def. Exhibit 2 Dkt. #81 pg 59.

**43.** Denied. Plaintiff's documentation included root cause analysis and hazard mapping. No contrary analysis has been submitted by Defendants. (Dkt. 40, 53, and 81)

**44.** Denied in part. Plaintiff was only aware of what the FDA inspector stated that the consumer had become ill— Def. Exhibit 2 Dkt. #81 pg 59. The Risk Analysis was developed from an independent review of policies, procedures, and operational documents or the lack thereof, relevant to FSMA and the FDA investigation and audit (Def. Ex 2-Dkt #81). There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**45.** Denied. Nestle's audit confirms that Defendants lacked change control (Def. Exhibit 6 ). Further, there was no evidence of change control. Plaintiff conducted her analysis consistent with her regulatory science background and job responsibilities in compliance with FSMA. There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**46.** Denied. Defendants failed to identify any scientific or regulatory basis for disputing Plaintiff's findings. The structure, content, and implementation of the cited plans failed to comply with the requirements of 21 C.F.R. Part 117, including the obligation to maintain a complete and site-specific Food Safety Plan for each facility (see 21 C.F.R. § 117.126(a)(1)). Moreover, Defendants did not demonstrate that the number or scope of plans aligned with the

hazard analysis and preventive control mandates applicable to each site. These deficiencies are further supported by the expert findings in the Dr. Catherine Hutt–Madison Declaration (Ex. 27) and (Dkt. #53 ¶¶60-61)

**47.** Denied. Plaintiff’s findings were specific, documented, and consistent with regulatory expectations under FSMA. Further, Defendants have not provided any admissible evidence to contradict this assertion. (Dkt.#81)

**48.** Plaintiff cannot address the thoughts and opinions of Defendants, as that is a subjective statement based upon mere conjecture. Further, Zicher raised similar concerns as Plaintiff but was not suspended or disciplined. (Answer ¶¶7, 60-61, 86 &99 Dkt. #53.)

**49.** Denied. Plaintiff did not discuss with Mr. Schroeder whether the Risk Analysis had been shared with Mr. Zicher. However, Defendants’ own audit logs reflect repeat nonconformities spanning multiple years under Zicher’s oversight (Dkt.#81- Ex 2 & 6), underscoring systemic quality failures. Defendants also claimed to maintain an open-door policy, and Mr. Schroeder admitted to routinely engaging with employees regarding operational issues, including nonconformances (Dkt. #53 ¶55-57 & fn. 88). This practice stands in stark contrast to Defendants’ newly asserted claim of a breached ‘corporate protocol’—a policy for which they have produced no written documentation or evidence of existence. The absence of such a policy further undermines the credibility of Defendants’ post hoc justification.

**50.** Admitted in part. Nestle also concurred in its audit that Defendants should not rely on the customer. (Defendants Exhibit 6, Plaintiff’s declaration Exhibit 10). Internal records show Zicher was involved in food safety planning and contributed to non-compliant documents identified by Plaintiff. i.e food safety plans. FSMA requires that Defendants engage in preventive risk-based

analysis—Food Safety Modernization Act. Plaintiff’s Risk Analysis addressed systemic issues that were validated by third-party and FDA findings. (Ex. 2; FDA Report, Def. Exhibit 5 and 6).

**51.** Admitted in part. Zicher was not responsive to the requests and queries made by the FDA inspector, as evidenced by the FDA inspector, who stated that she requested one document, but was provided another (Def. Exhibit 2 pg. 71) . And that document was hard to read and understand and had errors. Plaintiff asserted that the answers should be responsive to the questions and eliminate extraneous and erroneous information.

**52.** Denied. No documentation contradicts Plaintiff’s FSMA analysis; instead, Defendants removed her without refuting her specific findings (Dkt.#53 ¶¶ 26, 60-61 &75). Further, this contradicts Defendants’ Exhibit 3 of Dkt 81 that speaks about and clarifies the regulatory asks.

**53.** Denied. The SQF report (Def. Ex 5) clearly indicates that the X-ray machine is not GRAS and the Food Safety Plan that asserts such was drafted by Zicher. FSMA requires as part of its risk management, a preventive process control—preventive maintenance program. The manufacturers’ recommended maintenance may not support the FSMA requirement for the preventive maintenance program and validation requirements. The Risk Analysis was grounded in Plaintiff’s scientific training and audit experience and identified unmitigated FSMA risks that Defendants did not dispute (Dkt. # 40, 53 & 81). The Risk Analysis was grounded in Plaintiff’s scientific training and audit experience.

**54.** Admitted.

**55.** Denied. Zicher sent out several emails internally regarding the FDA audit and the five observations ( non-compliances). Further, the email captured the essence of the visit and is corroborated by the FDA report itself. Further, Defendants admit in its answer that Schroeder

spoke to Zicher and others about operational issues and non-conformances regularly. Defendants admit that Zicher was not disciplined despite known consumer complaints and quality concerns under his oversight. (DKt. #1-FDA consumer complaints, Def. Ex. 2-pg 58, 59 and 71, Def. Ex 5, Def. Ex 6, Undisputed facts 49-52)

**56.** Denied. Plaintiff and Zicher engaged in analogous compliance activities, yet Plaintiff alone was suspended. This supports a claim of disparate treatment. (Dkt.#53- ¶60-61)

**57.** Denied. The Nestle audit espouses systematic failures, as well as the Wilton/Trace Gains (Dkt #1), and SQF audit contexts. (Defendants Exhibit 6, Madison Declaration Exhibit 10). Further, Defendants acknowledged that there were deficiencies with Nestle (Dkt. # 81 ¶20)

**58.** Denied. When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings and consumer complaints to management, he put them on notice that there was a non-conformity. A nonconformity is a breach of fiduciary duty. (Def. Ex 2 and 6)

**59.** Admitted

**60.** Denied. When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings and consumer complaints to management he put them on notice that there was a non-conformity. In particular, the Nestle audit specifically states that a repeated infraction has occurred. A non-conformity is a violation of the FFDCA. (Def. Ex 2 and 6)

**61.** Denied in part. Zicher stated in his 2023 affidavit to the Department of Labour that the food safety plans were not compliant, in contradiction to the Defendants' expert witness who stated

that the food safety plans were compliant. Also see Dr. Catherine Hutt's Expert report- Madison Declaration Exhibit 27

**62.** Denied. Zicher affirmatively communicated to company leadership that their interpretation and application of FSMA mandates—particularly regarding the adequacy of Food Safety Plans and hazard analysis and other issues Plaintiff raised—were sufficient, despite clear regulatory deficiencies (Zicher Aff. ¶42-Dkt #81). These assurances directly contradicted Plaintiff's documented findings and contributed to the company's misinterpretation of its legal obligations under 21 C.F.R. Part 117. Zicher's influence not only undermined Plaintiff's credibility but also steered the organization away from compliance, reinforcing *the retaliatory context in which Plaintiff's objections were dismissed.*

**63.** Denied. Zicher's repeated assertions that certain FSMA-related tasks—such as maintaining adequate HACCP, Hazard Analysis, Food Safety Plans and prohibiting adulterated food from entering the stream of commerce (Dkt. #1 & Dkt. #53)—were unnecessary, contributed to a systemic misinterpretation of regulatory requirements. This conduct not only undermined Plaintiff's compliance-based assessments but also led Defendants to disregard critical mandates under 21 C.F.R. § 117.126(a)(1), which requires a written and facility-specific Food Safety Plan. The company's reliance on Zicher's guidance, despite Plaintiff's documented objections and expert-supported findings (see Madison Declaration-Ex. 27), evidences a pattern of internal misinformation that materially distorted the organization's understanding of its legal obligations.

**64.** Denied. The Nestle audit espouses systemic failures, as well as the Wilton/Trace Gains, and SQF audit contexts Def. Ex 2, 5 & 6 Dkt. #81 and Dkt #1). When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings, such as Wilton,

and consumer complaints to management he put them on notice that there were non-conformities that occurred over time. There is a mischaracterization of the Risk Analysis as a Legal Analysis

**65.** Denied. The issues discussed in the Risk analysis were issues that were well-known and had been discussed with Zicher and by Zicher over the course of time with other internal and external stakeholders.

**66.** Denied. Zicher affirmatively communicated to company leadership that their interpretation and application of FSMA mandates—particularly regarding the adequacy of Food Safety Plans and hazard analysis and other issues Plaintiff raised—were sufficient, despite clear regulatory deficiencies (Zicher Aff. ¶42-Dkt 81). These assurances directly contradicted Plaintiff’s documented findings and contributed to the company’s misinterpretation of its legal obligations under 21 C.F.R. Part 117. Zicher’s influence not only undermined Plaintiff’s credibility but also steered the organization away from compliance, reinforcing the retaliatory context in which Plaintiff’s objections were dismissed.

**67.** Denied. Zicher told Plaintiff on October 3, 2022, at the Benensivlle facility, while waiting for a potential MedFast, that he and Ron Sammath decided what Schroeder should be told. (Madison Declaration)

**68.** Denied. Defendants failed to include Plaintiff in any remediation planning or findings. (Dkt. #53 ¶75)

**69.** Denied. Defendants admitted that Schroeder regularly spoke to employees about issues. (DKt 53), if Zicher is the Director of Food Safety, it would be improbable that Schroeder did not speak with him about the vast issues surrounding FSMA compliance, including the SQF audit that Defendants are advancing and referencing in their Motion for Summary Judgment (Exhibit 81).

**70.** Denied. Zicher raised similar regulatory concerns and introduced adulterated product into the stream of commerce, and was not disciplined, despite at least three consumer complaints under his leadership. Defendants admitted as much. (Def. Ex 2; Dkt. #1 consumer complaints)

**71.** Denied. Plaintiff does not need to read the contractual agreement to know that Defendants and Nestle and its other customers are regulated by the FDA and subject to its regulatory scheme—Food Drug and Cosmetic Act.

**72.** Denied in part. Defendants' Exhibit 6 does not correspond to Plaintiff's Exhibit 10, as attached to Plaintiff's Declaration. The audit issues cited therein are not discretionary recommendations but rather compliance metrics, as indicated by the legend in Defendants' own exhibit. Moreover, Defendants have failed to authenticate Exhibit 6 as a true and correct copy, and Nestlé has not submitted any affidavit or declaration attesting to its accuracy or provenance. The document also materially diverges from Plaintiff's records, including those attached as Exhibit 10 and as exhibits to the Risk Analysis at issue—exhibits that Defendants notably omitted. Plaintiff admits in part, solely to the extent that, following her suspension and exclusion from Defendants' facility, she lacks personal knowledge or a legitimate basis to confirm whether the cited issues were subsequently resolved.

**73.** Denied to the extent that I was well qualified to perform the duties and tasks that I was hired to perform. Further, Defendants cannot point to any poor work performance by Plaintiff. (DKt #53 ¶92 ) Further, Defendants denied terminating Plaintiff Answer ¶11(b), Dkt. #53.) They removed termination from the Joint Status Report. Under the Illinois Personnel Record Review Act (820 ILCS 40/8), Defendants cannot assert termination or discipline that does not appear in Plaintiff's personnel file. Defendants continue to mischaracterize Plaintiff's Risk Analysis as a Legal Analysis.

74. Denied. Defendants have not provided any results of the investigation, nor have they provided any objectively verifiable data supported by fact, science or law, as neither LeMay or Schroeder are experts in Food Safety regulations. What is telling is Defendants abandoned their expert witness for LeMay and Schroeder who have no formal training in regulatory science nor even hold a PCQI certification.

Defendants' abandonment of their designated expert—whose opinions failed to satisfy the admissibility standards under Rule 702 of the Federal Rules of Evidence—renders their current reliance on self-styled internal “expertise” both procedurally improper and legally suspect. Having failed to meet their burden to present reliable, qualified expert testimony based on sufficient data and sound methodology, Defendants now attempt to recharacterize their own decision-makers as de facto experts to justify their actions. This post hoc maneuver not only circumvents the gatekeeping function of Rule 702 but also underscores the absence of contemporaneous, evidence-based rationale for the adverse actions taken against Plaintiff.

For the foregoing reasons Defendants' motion for summary judgment should be denied.

Respectfully submitted

Mary Madison

Dated July 7, 2025